Syntex-Verona
MOD007452154
1.5

11-14-78

SUMMARY OF FINDINGS

Inspection of this firm was conducted under CP 7356.002.

Previous inspections of this firm on 8/19/75 and 7/19-21/77 have been in compliance, however, the firm did receive a Regulatory Letter on 9/14/76 regarding label claims for Kastab which is the firm's brand of Menadione Sodium Bisulfite. Labeling for this product was changed and revised labeling has been submitted during the previous inspection.

This firm continues to operate as a basic manufacturer of bulk drugs, food and feed additives. These products include Clacium Pantothenate; choline chloride, both feed and pharmaceutical grade; calcium and sodium propionates and EDDI. (Ethylene Diamine Dihydriodide). The firm also manufactures Betaine Hydrochloride (food grade), Choline Bitartrate (food chemicals Codex), and Choline Dihydrogen Citrate (food grade).

During the current inspection, a number of objectionable conditions and GMP deviations were noted associated with the manufacture of various choline salts as well as EDDI. A large dead beetle was found in a drum of choline chloride crystals which were labeled as pharmaceutical grade. Dead beetles were also present in the building where this product is manufactured and packaged. The insect contaminated choline chloride was sampled as INV 79-124-319.

The building used for the manufacture of EDDI and choline salts was found to be in a poor state of repair and allowed avenues for insect entry. Some equipment deficiencies were also noted in association with this process.

With respect to the manufacture of EDDI and pharmaceutical grade choline salts, the firm continues to fail to test components. Master formulas do not contain approved labels and label control was found to be inadequate. Master formulas were found to contain significant changes with no explanation, dates or initials and in some cases were not being followed.

The firm has no written procedure for review and approval of production records prior to release of a batch and it was found that one lot of EDDI was released even though some of the production records were missing or incomplete.

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No. FY-426. Additional _____
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SUPERFUND RECORDS

It was also noted that the firm had previously rejected choline chloride due to the presence of "bug parts." However, the firm did not follow-up with steps to correct this situation.

At the conclusion of the inspection, FD-483 List of Observations was issued to Production Superintendent Austin Nally and discussion was held with him and Walter R. Friedhofen, Quality Assurance Manager. It was noted that the firm is in the process of making major changes in batch production records in accordance with GMP's. There was some question by Mr. Friedhofen regarding the applicability of GMP's to the firm's products since they are essentially bulk drug products.

In addition to the choline chloride crystals which were sampled for filth analysis, samples of choline chloride crystals and choline bitartiate were collected during the inspection per HFF-320 assignment memo dated 10/25/78. These samples were collected as INV 79-124-317 & 318 for submission to HFF-144 laboratory for ethylene chlorohydrin residue analysis.

During the inspection, a documentary sample of Vigofac premix containing unidentified growth factors was collected as DOC sample 79-124-315 for label review. This product was collected in response to HFV-236 assignment request dated 10/24/78.

GMP deviations associated with the manufacture of a lot of EDDI manufactured during the inspection were documented under DOC sample 79-124-316.

At the conclusion of the inspection management was given an inspectional warning and general correction of objectionable conditions was promised.

HISTORY OF BUSINESS

There have been some changes in the firm since the previous inspection. The Verona, Missouri plant continues to operate as a part of the Nutrition and Chemical Division of Syntex Agribusiness Inc. Division offices are located at 1915 W. Sunshine, Springfield, Mo. 65805. Syntex Agribusiness Inc., Nutritional and Chemical Division is a subsidiary of the Syntex corporation. Corporate offices for Syntex are located at 3401 Hillview Ave., Stanford Industrial Park, Palo Alto, California 94304.

The Nutrition and Chemical Division consists in part of manufacturing plants located at Springfield, Mo. and Verona, Mo. The Vice President and General Manager of Syntex Agribusiness Inc., who has responsibility for both Verona and Springfield plants is Godfrey J. Moll who is located at the Syntex Agribusiness offices at 1915 W. Sunshine. Purchasing, sales and promotion are handled via the Sunshine office and some laboratory support is provided by the Springfield manufacturing plant. The production manager for both plants is located at the Springfield manufacturing facility. The line of authority is as follows:

Production Superintendent Austin Nally (Verona)
Production Manager Larry Wakefield (Springfield)
Technical and Operations Director Rick Bagbee (Springfield)
Vice President and General Manager Godfrey J. Moll (Springfield)
President of Syntex Agribusiness Inc. vacant
Executive Vice President, Syntex Corp. Hans Wolf (Palo Alto, Calif.)

In addition to manufacturing a number of basic chemical products, the Verona facility is a manufacturer of a large number of custom premixes. The premix portion of the operation was not covered during this inspection.

A complete listing of products manufactured or distributed by the Syntex Nutrition and Chemicals Division is attached as Exhibit 1. Products manufactured (synthesized) by the Verona plant are indicated by a letter V in the margin.

PERSONS INTERVIEWED AND RESPONSIBILITY

Prior to my arrival at the manufacturing plant, I visited the Nutrition and Chemical Division offices located at 1915 W. Sunshine. Credentials were shown and FD-482, Notice of Inspection was given to Vice President and General Manager Godfrey J. Moll. Mr. Moll provided me with information regarding the chain of command as noted in the previous caption. While at the Sunshine street offices I obtained labeling, formulation and shipping records in conjunction with HFV and HFF assignments covered during the inspection. Credentials were shown to Mr. Arch Fletcher, Manager of Distribution and Customer Services prior to obtaining records and distribution information.

Upon arrival at the manufacturing plant on 11/15/78, Credentials were shown and FD-482 Notice of Inspection was given to Austin J. Nally, Production Superintendent. Credentials were also shown to Mr. Walter R. Friedhofen, Quality Assurance Manager who provided information regarding complaints and quality control procedures. Review of finished product assay results was conducted at the Springfield, Mo. manufacturing plant where the laboratory is located. Credentials were also shown to Larry Wakefield who is Production Manager for both facilities.

During the inspection, Richard S. Bagbee, Technical and Operations Director was interviewed regarding the manufacturing process for choline bitartrate and he did furnish information which I requested in this regard.

Also interviewed during the inspection was Lynn Hughes, Area 7 Supervisor. Mr. Hughes is responsible for supervision of the production of choline salts, EDDI and Panaplex 160.

Mr. Tony Newcomb, Manager of Quality Control furnished me with information regarding laboratory analysis results and process changes.

Attached as Exhibit 2 is a flow chart showing the organizational set up of Syntex Agribusiness Inc. and lines of responsibility.

Production organization for the firm is outlined in Exhibits 3-5 and includes the Springfield, Mo. plant.

RAW MATERIALS

Raw materials, both foreign and domestic, are purchased by the firm in accordance with purchasing department specifications. Raw materials utilized by the firm are received in various bulk containers including truck and rail car. Incoming raw materials are not tested for identity or purity, even those products for which a manufacturer's certificate of analysis is not received. (Item 8, FD-483). Consequently, incoming raw materials are not quarantined upon receipt.

Raw materials in use during the inspection were from major chemical suppliers. In the case of EDDI, iodine 99.5% is supplied by [redacted] Hydrazine, (64.0% H2N2) is supplied [redacted] Ethylene Diamine is supplied by the

Although raw materials are not routinely quarantined, sampled and identified prior to use, the firm does maintain receiving and usage records which enables a lot of ingredient to be traced to the finished product.

EQUIPMENT AND PROCESSES

The Verona facility continues to be located on approximately 100 acres near Verona, Mo. The complex consists of 21 buildings which are designated with a V preceding the building numbers. The following is a list of building numbers and some of the operations which are housed in the respective buildings.

Building Number	Operations
Building #1	Warehouse, dry choline and fish food manufacturing.
Building #2	Propionate manufacturing.
Building #3	50% dry Choline manufacturing.
Building #4	Storage.
Building #5	Maintenance building.
Building #6	Electrical room.
Building #7	Parts storage.
Building #8	Aqueous building slab.
Building #9	Premix manufacturing.
Building #10	Choline salts and EDDI manufacturing.
Building #11	Formerly used for beta alanine manufacturing which has been discontinued.
Building #12	Laboratory.
Building #13	Pan-plex drying.
Building #14	Solvent recovery building.
Building #15	Waste treatment plant.
Building #16	Finished product warehouse.
Building #17	Office and lunch room.
Building #18	Finished propionate storage.
Building #19	Fish food manufacturing.
Building #20	Storage.
Building #21	Irrigation control room.

A number of building deficiencies were noted associated with building V10, which is the EDDI and choline salts manufacturing building. This building is of steel construction and houses a number of glass line reactor vessels, filters, centrifuges and a tumble bug dryer. During the inspection it was noted that both large sliding doors and smaller exit doors do not fit tightly and the larger doors were open during production. Virtually all the screens in this building were cut or torn, apparently by employees, to reach the window handle to open the windows. I observed broken glass in at least a dozen windowpanes including those windows located next to the tumble bug dryer where finished product is exposed.

The steel walls of the building are corroded around the floor wall junction resulting in holes to the outside in these areas. There were also holes in the walls of the building where pipes exit the building as well as holes where pipes have been removed. The above items were listed as Item 1a-e, FD-483.

I estimated approximately 100 dead beetles present around the perimeter of the inside of building V10 also. (Item 4, FD-483). These beetles were similar to the beetle found in the drum of choline chloride crystals in building V11. Four dead beetles were collected from the floor of the building along the north wall and were submitted as sub #2 of INV 79-124-319.

Due to rains which fell during the inspection, standing water was present outside the south door of building V10 as well as in the adjacent loading dock. (Item 2, FD-483).

During the previous inspection, it was noted that the light fixture over the choline salt centrifuge was corroded, however this was corrected following the previous inspection. It was noted that the hood over this centrifuge, however, is corroded. (Item 3, FD-483).

During the inspection, peeling paint was observed to be present on the port-lids of reactors in building V10. (Item 7, FD-483). It was also noted that a wooden handle utensil is used to sample in-process products from these reactors. (Item 6, FD-483). The wooden handled utensil is a plastic beaker which is bolted to a long wooden stick. This utensil is used to sample more than one type of product.

Choline Salts Manufacturing

During the inspection, Mr. Richard S. Bagbee furnished me with a brief outline of the manufacturing process for choline bitartrate. The manufacture of choline chloride is similar to the choline bitartrate process. A copy of the basic chemical reaction is attached as Exhibit 6. A copy of the process description is attached as Exhibit 7. The process is essentially a reaction between trimethylamine and tartaric acid to form trimethylammonium tartrate which is then reacted with ethylene oxide to form choline bitartrate. The choline salt is crystallized from the solvent, centrifuged and dried in the tumble bug dryer. Choline bitartrate is then either packaged in poly-lined fiber drums for distribution or is shipped to the Springfield, Mo. plant for classification or coating with [redacted]Silica aero gel. In the case of choline chloride, it is not coated but may be classified.

During the inspection, samples of four lots of choline chloride crystals on hand at the firm were collected as INV 79-124-318. This sample of choline chloride was submitted to the HFF-144 laboratory for ethylene chlorohydrin residue analysis.

Four lots of choline bitartrate were also sampled under INV 79-124-317. Since some of these lots were in quarantine when samples were collected, the firm did furnish me with analytical results for choline bitartrate prior to the end of the inspection. A copy of the analytical results is attached as Exhibit 8. Since run #873-B was rejected by the firm due to the presence of [redacted] a carbon-type filter aid, this sample was not submitted for analysis although it does appear on the receipt for samples.

EDDI Manufacturing

EDDI is also manufactured in building V10. EDDI is manufactured in the following manner. A glass lined 1,000 gallon reactor is charged with water and metallic iodine. Ethylene diamine is added to the reactor [redacted] Hydrazine is then slowly charged into the reactor and the operator observes the solution for a color change at which time the pH is checked. The product is treated wit[redacted] stirred and filtered and a slurry is then formed from the resulting solution [redacted] The slurry is [redacted] and subsequently cooled to [redacted]. The crystals are then centrifuged and washed and are dried in the tumble bug dryer and packaged into 10 gallon poly-lined drums.

During the inspection, a number of GMP deviations were noted associated with EDDI manufacture. For example, the master formula for EDDI failed to contain approved labeling. Also, the master formula contained significant changes with no explanation, dates or initials and, in some cases, the master formula was not being followed. In the case of EDDI, Run #1825, the master formula shows the solvent to be used as [redacted] whereas the batch record shows [redacted] scratched out and [redacted] used instead. There are no initials or explanation for the change in the batch record.

The master formula for EDDI also shows the drying temperature as [redacted] degrees. It was noted that the drying log for this run shows a drying temperature [redacted]s. In the area where the drying log was located, the area supervisor had prepared drying times and temperatures for a number of different products. The drying time for EDDI was listed as [redacted]. There is no notation as to who prepared the drying sheet, whether or not it was approved and checked, or the date it was prepared.

Another discrepancy was noted associated with this run of EDDI. There are two recorder charts involved in the production of a lot of EDDI, one for each of two reactors. The recorder chart which shows the Hydrazine reaction temperature was missing for Run #1825, and the remaining recorder chart was inadequately identified, in that it did not designate the reactor from which it was recording. Recorder charts for other runs were observed stored in a stack in the operator's desk in the manufacturing area, rather than in with other batch records.

The Hydrazine tank is located near one of the reactors, and contains a sight glass with a tape measure. A chart is posted near the Hydrazine tank to enable the operator to make necessary calculations to determine the correct amount of Hydrazine to add to the batch. I observed that the operator's Hydrazine tank calculations were written on the tank and were not reflected in the batch records.

There were other discrepancies observed associated with EDDI, Run #1825. Not all entries were made in the batch record, and missing entries included "Time Batch Started," initials of the person carbon-treating and filtering the product, "Cooling Finish Time," and initials of individual performing this operation, and "Drying Finish Date," "Time," and initials. It was noted that the drying log, which is separate from the batch record, does reflect the date, time and temperature of the drying of the run, as well as the yield; however, this log is not maintained with the batch record and contains no identification of the individual conducting the operation. The batch records also fail to show that each significant step in the process is checked by a second individual.

In addition, there is no procedure for the review and approval of production records prior to release of a batch. In the case of EDDI, Run #1825, the lot was released on 11/13/78, even though some of the batch record was incomplete and the recorder chart was missing.

The above discrepancies were listed as Items #9-#14, FD-483.

After a lot is manufactured, dried and packaged, a pink "QUARANTINE" sticker is placed on the container, and it is placed in a warehouse awaiting quality-control release. In the case of EDDI, laboratory analysis is done at the Springfield, Missouri, manufacturing plant. Upon the receipt of satisfactory laboratory analysis results, the pink "QUARANTINE" sticker is removed from the drums, and it is replaced with a "RELEASE" sticker. An example of a "QUARANTINE" tag for EDDI is attached as Exhibit #9. In the case of feed-grade products such as EDDI, the "RELEASE" sticker is yellow. (Exhibit #10.) Food or pharmaceutical-grade products are labeled with a white "RELEASED" label. Copies of Choline Bitartrate "QUARANTINE" and "RELEASE" labels are attached as Exhibits #11 and #12, respectively.

Most of the firm's products are not labeled until just prior to shipment. A label order request is prepared, and labels are counted, coded and issued by the label clerk. A copy of the label order request form is attached as Exhibit #13. Labels are reconciled by the label clerk, and the label inventory is maintained in a bound book in the label storage room which is located in the firm's laboratory building.

During the inspection, the individual normally responsible for label issuance had recently quit,. The firm's label inventory for two different types of EDDI labels was checked, and both were found to be inadequate. The label inventory for EDDI 100-lb. labels was short seven labels, and the inventory for other EDDI labels was 36 labels short. The labels were not being reconciled during the inspection. (Item #10, FD-483.)

Discrepancies associated with master formula and production records for EDDI, Run #1825, were documented under Sample DOC 79-164-316.

PROPIONATE MANUFACTURE:

Sodium and Calcium Propionate manufacture is accomplished in Building #2. The manufacturing process for this product is the following: Lime is slaked, charged into a reactor, and Propionic Acid is added. A flocculating agent is added, and the tank is allowed to settle.

The Calcium Propionate solution is drawn off into a filtering tank, and the liquid is filtered using filtering agents. The pH is adjusted and the product is dried on one of the several drum-type roller driers. The product is augered from the driers to a hammer mill, and then the product is packaged in drums or paper bags. No significant objectionable conditions were noted associated with the Propionate operation.

FERMASOL LABELING:

During this inspection, HFV-236 Assignment #78-150, dated 10/24/78, was covered. The assignment, copy attached, requested an official documentary sample, including qualitative and quantitative formula, labeling, promotional material and marketing history, for a product called Hoffman Bonded Fermasol. The assignment listed Hoffman-Taff, Inc., Manufacturing Chemists, Springfield, Mo., as the manufacturer.

Although the firm does manufacture and distribute a product called Fermasol, the firm has not used the Hoffman-Taff name since about January, 1974.

Syntex acquired Hoffman-Taff in 1969. In 1970-73 the firm was operated as Hoffman-Taff, Inc., a subsidiary of Syntex Labs, Inc. About January, 1974, Syntex Agribusiness Inc. was formed, and Hoffman-Taff was dropped from labeling, letterheads and advertising in favor of the Nutrition & Chemical Division of Syntex Agribusiness Inc.

A copy of current Fermasol labeling was obtained during the inspection and is attached as Exhibit #14. The current label is scheduled to undergo revision since the firm can no longer obtain whey fermentation solubles which are used in this product. Current Fermasol labeling contains no reference to unidentified growth factors; however, the firm's most recent product list, dated 4/78 (Exhibit #1) does make reference to unidentified factors and unidentified nutrients in this product.

During the inspection, it was noted that the formula used in the manufacture of Fermasol is also used in two other products. These are Vigofac-6-F and Dietazol. Dietazol is Syntex' export label, and Vigofac-6-F is manufactured for Pfizer, Inc.; however, Syntex' name appears on the label. Vigofac-6-F is a Pfizer trade-name. Vigofac-6-F is also reportedly for export only. It does contain references to unidentified growth factors. Labeling and formulation were collected under Sample DOC 79-124-315 for label review by HFV-236.

PREMIX OPERATIONS:

The firm also has a custom premix manufacturing operation at the Verona plant which is housed in Building #9. The firm manufactures a variety of medicated and non-medicated premixes on a custom basis. The premix operation was not covered during this inspection.

MANUFACTURING CODES:

For products manufactured during the inspection, the firm utilizes both a run number and a lot number. The lot number is a consecutive number which is assigned to a product after it has passed quality-control testing. The run number is also a consecutive number; however, the numbers do not necessarily coincide since a particular run may be rejected for plant use or rework. Lot numbers are also prefaced with letters which designate the product. For example, EDDI lot numbers are prefaced with the letters, EDS-****. Choline Chloride lot numbers are preferenced with CC-**, Choline Bitartrate is prefaced with the letters B-****, etc.

LABORATORY CONTROLS:

Laboratory testing is done both at the Verona plant and the Springfield plant. In the case of Choline Salts and EDDI, finished-product assays are run at the Springfield, Missouri manufacturing plant.

I did visit the Springfield facility and reviewed a representative number of laboratory results for Choline Chloride, Choline Bitartrate, and EDDI.

During the review of laboratory results, it was noted that the laboratory report for Choline Bitartrate, Lot CBS-724, was rejected due to containing bug parts. This particular lot was run at the Verona plant; however, it was also coated and classified at the Springfield plant. Apparently, the only follow-up was rejection of the lot.

Also, there were no written records of the investigation, conclusions and follow-up for other reject products.

COMPLAINT FILES:

During the inspection, the firm's complaint files were reviewed for a period of approximately six months prior to the inspection. Most complaints involved feed-grade Choline salts, and were due to the tendency of the product to cake.

The only significant complaint was dated 6/13/78 and was registered by [redacted] rejected 4/50-kg. drums of Choline Chloride Crystals, Lot CC618, 613 and 576, due to the presence of foreign material. The complaint reported that the foreign material looked like rust; however, Syntex' analysis was negative for iron. The reserve sample analysis showed little or no extraneous material in the product.

DISTRIBUTION:

Copies of Syntex invoices showing recent shipments of EDDI and Choline Salts are attached as Exhibits #15-#26.

LABELING & PROMOTION:

Copies of Choline Chloride, Choline Bitartrate and EDDI labeling are attached as Exhibits #27-#29. Fermasol labeling and formulation is submitted as a part of Sample DOC 79-124-315. Product descriptions and specifications are included in the firm's product list and product information booklet, Exhibit #1.

SAMPLES:

Three physical and two documentary samples were collected during the inspection.

DOC 79-124-315--This is a documentary sample of Vigofac-6-F Premix, which is an export product. This product is identical to Fermasol, and Fermasol labeling is also attached.

DOC 79-124-316--This is a documentary sample of EDDI, Run #1825, which was collected during the inspection to document GMP deviations. It was noted that the firm does consider these records confidential, and they were so identified by Mr. Friedhofen, Quality Assurance Manager. A copy of the Continuation Sheet for this sample is attached as Exhibit #30, and lists discrepancies documented by collection of this sample.

Sample INV 79-124-317--This sample consists of four subs representing four different lots of Choline Bitartrate Crystals which were collected per HFF-320 Assignment for Ethylene Chlorhydrin residues. Sub #1 is Lot B-1645; Sub #2 is B-1620; Sub #3 is 867R, with Sub #4 being 868R.

Syntex' analytical results for these lots are attached as Exhibit #8.

INV 79-124-318--This is a sample of Choline Chloride Crystals, also collected per HFF-320 Assignment, and also represents four lots on hand at the firm. Sub #1 is Lot CC-637; Sub #2 is CC-636; Sub #3 is CC-639; and Sub #4 is CC-641.

INV 79-124-319--This sample represents Choline Chloride Crystals collected from a drum in Lot #CC-635, which contained a dead beetle. Dead beetles from the floor along the wall in the Choline Salts manufacturing building were also collected as part of this sample. The lot was rejected by Production Manager Larry Wakefield. When the insect was noted, management did state that partial drums of product were considered tads and were reprocessed; however, this product was in the released-product portion of the warehouse, and the firm had been making shipments from this lot. Area Supervisor Lynn Hughes did state that if orders were received for a small amount of product that it could be filled from lots such as these.

CORRECTIONS:

Following the previous inspection, production superintendent Austin Nally stated that the firm had corrected all objectionable items listed. Most of the items dealt with discrepancies in the premix area which was not covered during this inspection.

I did note several items which were listed on the FD-483 following the previous inspection which had, in fact, been corrected. It was noted that the firm did replace the corroded light fixture over the Choline Salts centrifuge; however, it was noted during this inspection that the hood above the light fixture was corroded.

The firm did install a shelf for the storage of utensils used in handling the product.

It was also determined that the firm currently has specifications for the laboratory release of three-Nitro Premix.

DISCUSSION WITH MANAGEMENT:

At the conclusion of the inspection, FD-483, List of Observations, was given to Production Superintendent Austin Nally, and discussion was held with him and Quality Assurance Manager Walter R. Friedhofen.

Also present during the discussion was Mr. William J. Zay, the former plant manager. Mr. Zay is currently responsible for a number of in-plant programs such as safety, etc.

During the inspection, Mr. Friedhofen had furnished me with copies of the firm's new batch-record forms. Copies of the blank forms are attached as Exhibits #31-#33. Mr. Friedhofen did point out that the firm is in the process of reviewing all procedures and operations, and the firm intends to apply GMP requirements to all products in the immediate future.

Regarding the building defects listed as Item #1, FD-483, I pointed out that the building was not adequate for operations where products are exposed. I noted that the beetles found along the walls in the Choline Salts building appeared to be identical to the beetle found in the drum of Choline Salts which was sampled earlier. Regarding this item, I also questioned the adequacy of the dust-control in this area.

Regarding the standing water present outside the south door of Building V-10, as well as the loading-dock area, there was little discussion regarding this item since it was obvious during the inspection.

Regarding the hood over the Choline Salts centrifuge, Mr. Nally pointed out that a new stainless-steel hood has been on order for approximately two months from the [redacted] He offered to show me the order for this hood, and I stated that it would not be necessary, and that I would note in my report that a new hood had been ordered.

The gentlemen made no specific comments regarding the dead beetles present around the perimeter of the inside of Building V-10, or the dead beetle present in the drum of Choline Chloride other than to acknowledge that these items had been noted.

Regarding the wooden-handled utensil used to sample in-process products, I pointed out that the wood could not be adequately cleaned and could provide an avenue for cross-contamination. Mr. Nally stated that the firm would attempt to obtain a utensil of plastic material of some type.

Regarding the peeling paint present on the port lids of reactors in Building V-10, Mr. Nally asked me what I felt the significance of this item was. I told him that it showed me that maintenance of the equipment was lax, and that pieces of paint chips could fall into the product.

Mr. Nally voiced the opinion that filtration of the product would eliminate any problems of this nature.

Regarding the firm's failure to test components, Mr. Friedhofen stated that he was not sure if he agreed with this observation. He felt that this was not a GMP requirement and did not apply to this firm's products at any rate. He did state that he felt that Iodine, for example, was not a component of EDDI, but was a reaction product. He stated that the firm felt that if reagents were not satisfactory, the reaction would not go.

Regarding inadequate label control, Mr. Friedhofen was present when the label inventory discrepancy was noted. I pointed out at the time that although the firm's regular employee in this area had recently quit, the firm had no written procedures so another person could step in and maintain label control.

Regarding master formula discrepancies, Mr. Nally stated that he had personally seen to it that discrepancies such as a lack of dates and initials, changes and different ingredients were corrected prior to the end of the inspection.

Regarding the inadequate identification of the recorder chart for EDDI, Run #1825, Mr. Nally asked me specifically what I meant. I pointed out that there was no indication on the recorder chart which reactor the temperature was being recorded on.

Management indicated at this point that until new batch records become instituted, all pertinent charts and logs will be attached to the batch records. It was pointed out that record-keeping discrepancies would be corrected when the new record-keeping system is instituted. This was also noted in response to Item #13, which is the lack of a procedure for review and approval of production records prior to release of a batch. It was noted that the new batch records are designed for final review and approval.

Regarding the firm's inadequate follow-up of reject material, I pointed out that the firm's own analysis of a previous batch of choline Bitartrate had revealed bug parts. I pointed out that there were only a couple of areas where product is exposed during the manufacturing process. I pointed out that a follow-up such as a physical inspection of the facilities was not done by the firm, nor were any investigation results and conclusions made in writing other than the rejection of the batch.

I pointed out to Mr. Friedhofen and Mr. Nally that product containing bug parts was adulterated and was in violation of the Act. In this regard, I read Sections 301(k), 402(a)(4), and 501(a)(1)&(2). During this time, Mr. Friedhofen indicated that he was well aware of the requirements of the FD&C Act, as well as the GMP's.

Although Mr. Friedhofen did question the applicability of the GMP's to his firm's bulk drug products, I pointed out that the FD&C Act did not distinguish between bulk and finished pharmaceuticals as did the GMP's. I also pointed out that the Act prohibited doing anything with respect to a food or drug which resulted in its becoming adulterated or misbranded.

In summary, management indicated that a number of corrections would be made when the firm was able to institute the revised record-keeping system; however, no specific commitments were made regarding what action the firm would take with respect to the Choline Salts and EDDI manufacturing building.

EXHIBITS:

Exhibit #1: Syntex catalog and product information booklet.

Exhibit #2: Flow sheet for the organization of Syntex Agribusiness, Inc.

Exhibits #3-#5: Outline of the production organization for Springfield and Verona plants.

Exhibit #6: Diagram of the reactions involved in the manufacture of Choline Bitartrate.

Exhibit #7: Copy of the process description for Choline Bitartrate.

Exhibit #8: Choline Bitartrate analytical results.

Exhibit #9: Quarantine tag for EDDI.

Exhibit #10: Release tag for EDDI.

Exhibit #11: Quarantine tag for Choline Chloride.

Exhibit #12: Release tag for Choline Chloride.

Exhibit #13: Label order request.

Exhibit #14: Fermasol label.

Exhibits #15-#26: Syntex invoices covering recent shipments, which are of EDDI, Choline Salts and Fermasol.

Exhibits #27-#29: Copies of labeling for EDDI and Choline Salts.

Exhibit #30: C/R Continuation Sheet outlining record-keeping deficiencies documented as DOC Sample 79-124-316.

Exhibit #31: through Exhibit #33: New batch-record forms.

TLA:rpp
12/11/78

Ted L. Anderson (252)
Investigator (SPG-RP)

U. S. ENVIRONMENTAL PROTECTION AGENCY

REGION ___

POTENTIAL HAZARDOUS WASTE SITE

SITE INSPECTION REPORT

Lynday Verona
MOP0074521S4
Break: 1.5
Other:
10-30-79

SITE IDENTIFICATION

Site number (obtain from Headquarters) _____

Site Name Verona, Missouri, Syntex Dioxin Waste Storage Tank

Street (or other) identifier) Syntex Agribusiness (Nutritional and Chemical Div.

City, State, Zip P.O. Box 1246 S.S.S. Springfield, Mo 65805

County Name Lawrence

Operator of Site Syntex Agri-business 417-866-7291
Telephone

Street See above

City, State, Zip "

Owner of Realty Syntex Agri-business
(if different from operator of site) Telephone

City, State, Zip _____

Site Description _____

Ownership /__/ Federal /__/ State /__/ County
/__/ Municipal /X/ Private

Fill in pages 2 through 13 of this form as completely as possible. Then use the information on this form to develop a Tentative Disposition.

Estimate date of Tentative Disposition _____

Apparent seriousness of problem /__/ High /__/ Medium /X/ Low /__/ None

File this form in its entirety in the regional Hazardous Waste Log File. Be sure to include all appropriate supplemental forms in the file. Submit a copy of the forms to:

Site Tracking System
Hazardous Waste Enforcement Task Force
U. S. Environmental Protection Agency
401 M Street SW (EN335)
Washington, D. C. 20460

Prepared by Kenneth S Ritzky

Telephone FTS 758-3307

Date 10-30-79

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SUPERFUND RECORDS

U. S. ENVIRONMENTAL PROTECTION AGENCY

REGION ___

POTENTIAL HAZARDOUS WASTE SITE

SITE INSPECTION REPORT

SITE IDENTIFICATION

Site number (obtain from Headquarters) _____

Site Name Verona, Missouri, Synex Diesel waste storage tank

Street (or other) identifier) Synex Agribusiness Warehouse and Chemical Dan

City, State, Zip P.O. Box 1240 S.S. Springfield, Mo 65-805

County Name Lawrence

Operator of Site Synex Agribusiness 417-866-7241 Telephone

Street See above

City, State, Zip ---

Owner of Realty Synex Agribusiness
(if different from operator of site) Telephone

City, State, Zip _____

Site Description _____

Ownership /__/ Federal /__/ State /__/ County
/__/ Municipal /X/ Private

Fill in pages 2 through 13 of this form as completely as possible. Then use the information on this form to develop a Tentative Disposition.

Estimate date of Tentative Disposition _____

Apparent seriousness of problem /__/ High /__/ Medium /X/ Low /__/ None

File this form in its entirety in the regional Hazardous Waste Log File. Be sure to include all appropriate supplemental forms in the file. Submit a copy of the forms to:

Site Tracking System
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Telephone FTS 758-3307

Date 10-30-79

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INSPECTION INFORMATION

Principal Inspector: Kenneth Bierly — Environmental Scientist (Title)

EPA Region VII (Organization) — 816-374-3307 (Area Code and Telephone)

INSPECTION PARTICIPANTS

Names	Robert Busby	Kenneth Bierly	
Organization	EPA Region VII	EPA Region VII	
Telephone	FTS 758-3307	FTS 758-3307	

SITE REPRESENTATIVES INTERVIEWED (Corporate Officials, Workers, Residents)

Names	Mr. Godfrey Moll		
Title/Telephone	Vice President & General Manager		417-866-7291
Address	P.O. Box 1246 S.S.S.		
	Springfield, Mo 65805		
Names			
Title/Telephone			
Address			

GENERATOR INFORMATION (List sources of waste)

Names	NEPACCO		
Telephone	Out of business (unknown)		
Address			
Waste Type Generated			

TRANSPORTER/HAULER INFORMATION

Names	NA		
Telephone			
Address			
Waste Type Transported			

If waste is processed on site and also shipped to other sites, identify off-site facilities used for disposal:

Names	NA		
Telephone			

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INSPECTION INFORMATION (Continued)

Date of Inspection 7-12-79 Time of Inspection _____

Access gained by /X/ Permission /__/ Warrant
(Credentials must be shown in all cases)

Weather Clear

SAMPLING INFORMATION

Check off the types of samples taken and indicate where they have been sent e.g. regional lab, other EPA lab, contractor, etc. and estimate when the results will be available.

SAMPLE TYPE	COLLECTED	REMARKS	ESTIMATE DATE THAT RESULTS WILL BE AVAILABLE
Groundwater	/__/ Yes		
Surface Water	/__/ Yes		
Waste	/__/ Yes		
Air	/__/ Yes		
Runoff	/__/ Yes		
Spill	/__/ Yes		
Soil	/__/ Yes		
Vegetation	/__/ Yes		
Other_____	/__/ Yes		

FIELD MEASUREMENTS TAKEN (E.g. radioactivity, explosivity, PH, etc.)

Type	Location of Measurements	Results

Photos Taken /X/ Ground /X/ Aerial Photos in custody of Region II EPA

Site Mapped /__/ Yes Location of Maps _____

Latitude /__/__/ deg /__/__/ min /__/__/ sec Longitude /__ /__/__/ deg /__/__/ min /__/__/ sec

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SITE INFORMATION

/_/ ACTIVE — Those industrial or municipal sites which are being used for waste treatment, storage, or disposal on a continuing basis, even if infrequently.

/X/ INACTIVE — Those sites which no longer receive wastes.

/_/ OTHER — Specify: _____
Those sites resulting from incidents like "midnight dumping" where no regular or continuing use of the site for waste disposal has occurred.

GENERATOR ON SITE No /X/ Yes /_/ If yes, specify generator's SIC Code /_/_/_/_/

Area of Site _____ Acres

Are there buildings on the site No /_/ Yes /X/ If yes, specify Synthetic Agribusiness Plant

CHARACTERIZATION OF SITE ACTIVITY

Check off one or more of the activities below:

/_/ TRANSPORTER	/X/ STORER	/_/ TREATOR	/_/ DISPOSER
/_/ Rail	/_/ Pile	/_/ Filtration	/_/ Landfill
/_/ Ship	/_/ Surface Impoundment	/_/ Incineration	/_/ Landfarm
/_/ Barge	/_/ Drums	/_/ Volume Reduct	/_/ Open Dump
/_/ Truck	/X/ Tank, Above Ground	/_/ Recycling/ Recovery	/_/ Surface Impoundment
/_/ Pipeline	/_/ Tank, Below Ground	/_/ Chem/Phys Treatment	/_/ Midnight Dumping
/_/ Other _____	/_/ Other _____	/_/ Biological Treatment	/_/ Incineration
		/_/ Waste Oil Reprocessing	/_/ Underground Injection
		/_/ Solvent Recovery	
		/_/ Other	/_/ Other

SUPPLEMENTAL FORMS

If the site falls within any of the categories listed below, supplemental forms must be filled out. Indicate which supplemental forms you have filled out and attached to this form:

/X/ Storage	/_/ Incineration	/_/ Landfill
/_/ Surface Impoundment	/_/ Deep Well	/_/ Chem/Bio/Phys Treatment
/_/ Landfarm	/_/ Open Dump	/_/ Transporter
/_/ Recyclor/Reclaimer		

WASTE RELATED INFORMATION

WASTE TYPE:

/X/ LIQUID /__/ SOLID /__/ SLUDGE /__/ GAS

WASTE CHARACTERISTICS:

/__/ CORROSIVE /__/ IGNITABLE /__/ RADIOACTIVE /__/ HIGHLY

/X/ TOXIC /__/ REACTIVE /__/ INERT /__/ FLAMMAB

/__/ OTHER SPECIFY_____

WASTE CATEGORIES:

Are records of wastes available? Specify items such as manifests, inventories, etc:

Yes, Syntex Agribusiness has chemical waste by analysis.

Estimated amount of waste by category and specify details below:

SLUDGE	OIL	SOLVENTS	CHEMICALS	SOLIDS	OTHER
_____	4,300 gallons	_____	_____	_____	_____
amt & unit	amt & unit	amt & unit	amt & unit	amt & unit	amt & unit
/__/ Paint, Pigments	/X/ Oily Wastes	/__/ Halogenated Solvents	/__/ Acids	/__/ Flyash	/__/ Lab,P
/__/ Metals Sludges	/__/ Other _____	/__/ Non-halogntd Solvents	/__/ Pickling Liquors	/__/ Asbestos	/__/ Hospi
/__/ POTW		/__/ Other _____	/__/ Caustics	/__/ Milling	/__/ Radio
/__/ Alum Sldg			/__/ Pesticides	/__/ Mine Tailngs	/__/ Munic
/__/ Other _____			/__/ Dyes/Inks	/__/ Ferrous	/__/ Other Specif
			/__/ Cyanides	/__/ Non-ferr	_____
			/__/ Phenols	/__/ Other _____	_____
			/__/ Halogens		_____
			/__/ PCB		_____
			/__/ Metal Solvents		
			/__/ Other _____		

LIST SUBSTANCES OF GREATEST CONCERN WHICH ARE ON THE SITE: (place in descending order of

	Substance	Form (Solid, Liq, Vapor)	Toxicity (High, Med, Low, None)	CAS Number	Amount and Unit
1	TCDD	Liq	High	_____	343 - 4,300 gallons ± 17ppm
2	_____	_____	_____	_____	_____
3	_____	_____	_____	_____	_____
4	01606	_____	_____	_____	_____

HAZARD DESCRIPTION

FIELD EVALUATION	HAZARD DESCRIPTION	REMARKS
Check below if "yes"		
/X/	Human Health Hazards	This material (7CDD) has a reported (NIOSH Registry) TDL_0 of 280 ng/kg for SKN-hmn.
/__/	Non-Worker Injury/Exposure	
/__/	Worker Injury/Exposure	
/__/	Contamination of Water Supply	
/__/	Contamination of Food Chain	

HAZARD DESCRIPTION

FIELD EVALUATION	HAZARD DESCRIPTION	REMARKS
Check below if "yes"		
/__/	Contamination of Ground Water	
/__/	Contamination of Surface Water	
/__/	Damage to Flora/Fauna	
/__/	Fish Kill	
/__/	Contamination of Air	

HAZARD DESCRIPTION

FIELD EVALUATION	HAZARD DESCRIPTION	REMARKS
Check below if "yes"		
/__/	Noticeable Odors	
/__/	Contamination of Soil	
/__/	Property Damage	
/__/	Fire or Explosion	
/__/	Spills/Leaking Containers/Runoff Standing Liquid	

HAZARD DESCRIPTION

FIELD EVALUATION	HAZARD DESCRIPTION	REMARKS
Check below if "yes"		
/__/	Sewer, Storm Drain problems	
/__/	Erosion Problems	
/__/	Inadequate Security	
/__/	Incompatible Wastes	
/__/	Midnight Dumping	

FIELD EVALUATION	HAZARD DESCRIPTION	
Check below if "yes"		REMARKS
/__/	Other - Specify	

POPULATION DIRECTLY AFFECTED BY SITE:

potentially	Approximate number of People Affected	Within unit Area	Approximate Number of Buildings Affected	Distance to Site
In residential areas	515	1 mile radius	~200	~100 yards
In commercial or industrial areas				
In publicly travelled areas				
Public Use Areas (Parks, Schools, etc.)				

WATER AND HYDROLOGICAL DATA

Depth to Groundwater Infiltr. flow   Direction of Flow ______

Groundwater use in vicinity Drinking water   Potential yield of Aquifer Unknown

Distance to Drinking Water Supply ~500 yards   Direction to Drk Wtr Suppl On Syntex Site

Type of Drinking Water supply /__/ Non-Community < 15 connections   /__/ Community (Town of 5,847 >15 connections

/__/ Surface Water   /X/ Well

List all drinking water wells within 1/4 mile radius of site:

Well	Depth	Location (proximity to population/buildings)	Non-Community
# 3		On Syntex Site	/__/
			/__/
			/__/
			/__/
			/__/

Receiving Waters   /__/ Sewers   /X/ Streams/Rivers

Name ______   /__/ Lakes/Reservrs   /__/ Other ______

Specify use and classification of receiving waters Trout Reservoir and trout streams

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SOIL AND VEGETATION DATA

Location of Site is in:

/__/ Known Fault Zone

/X/ Karst Zone potentially

/X/ 100 Year Floodplain

/__/ Wetland

/__/ A Regulated Floodway

/__/ Critical Habitat

/__/ Recharge Zone or Sole Source Aquifer

TYPE OF GEOLOGICAL MATERIAL OBSERVED

	/X/ Overburden	/__/ Bedrock (specify)	/__/ Other (specify)
/X/	Sand	_____	_____
/__/	Clay	_____	_____
/__/	Gravel	_____	_____

SOIL PERMEABILITY

/X/ Unknown

/__/ Moderate (10 to .1 ft/day)

/__/ Very High (100000-1000 ft/day)

/__/ Low (.1 to .001 ft/day)

/__/ High (1000-10 ft/day)

/__/ Very Low (.001 to .00001 ft/day)

Recharge Area /X/ Yes /__/ No Comments: waste is in storage tank with concrete base

Discharge Area /X/ Yes /__/ No Comments: Unknown

Slope (estimate % of slope) _____ Specify direction of slope, condition of slope, etc.

Other Geological Data _____

_____

_____

PERMIT INFORMATION

List all Applicable Permits held by the site:

Permit Type (E.g. RCRA, State, NPDES, etc)	Issuing Agency	Permit Number	Date Issued	Expirtn date	In Compliance Yes	No	U:
					/_/	/_/	
					/_/	/_/	
					/_/	/_/	
					/_/	/_/	
					/_/	/_/	
					/_/	/_/	

PAST REGULATORY OR ENFORCEMENT ACTIONS

/X/ None

/_/ Yes If yes, summarize: Explain

Based on the information on pages 2 through 13, fill out the projected date of the Tentative Disposition on the first page of this form.

Supplemental Form

Land Farm

Answer and explain as necessary:

1. State permit yes ( ) no ( )

2. Area (dimensions of site):_____

3. Application rate_____

4. Improper Disposal of Unauthorized Material in Land Farm yes ( ) no ( )

5. Diversion structures are Effectively Constructed and Properly Maintained yes ( ) no ( )

6. Evidence of Ponding of Liquid on Site yes ( ) no ( )

7. Odors (especially hydrogen sulfide) Yes ( ) No ( )

   indicate:_____

_____

_____

8. General Physical appearance of soil (color, clasticity, etc):_____

_____

_____

_____

9. Vegetation on Landfarm:_____

_____

_____

10. pH:_____

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Supplemental Form

Storage Facilities

Answer and explain as necessary.

1. Storage Area has Continuous Impervious Base yes (X) no ( )

2. Storage Area has a Confinement Structure yes (X) no ( )

3. Evidence of Leakage/Overflow yes ( ) no (X) (Document where and how much runoff is overflowing or leaking from containment)

4. Estimate Type and Number of Barrel/Containers: 1 @ Steel Tank

5. Glass or plastic storage containers used Yes ( ) No (X)

6. Estimate Number and Capacity of Storage Tanks: Tank capacity ~ 8,000 gallons per container 4,700 gallons Still resides

What do U mean?

7. Note Labeling on Containers:

8. Evidence of Leakage Corrosion or Bulging of Barrels/Containers/Storage Tanks yes ( ) no (X) (Document evidence. Describe location and extent of damage. Photograph)

9. Direct Venting of Storage Tanks yes ( ) no (X)

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10. Check Area for Containers Holding Incompatible Substances
Yes ( ) No (X) (If yes, document evidence. Describe location and identity of hazardous waste. Photograph).

11. Check area for storage at incompatible substances stored in close proximity. Yes ( ) No (X) (If yes, document evidence. Describe location and identity of hazardous waste. (Photograph)

NA 12. Adequate Container Washing and Reuse Practices Yes ( ) No ( )

NA 13. Adequate Practices for Disposal of Empty Storage Containers
Yes ( ) No ( )

U. S. ENVIRONMENTAL PROTECTION AGENCY

REGION VII

POTENTIAL HAZARDOUS WASTE SITE

TENTATIVE DISPOSITION

SITE IDENTIFICATION

Site number _____

Site Name Verona, Missouri, Syntex Dioxin Storage Site

Street P.O. Box 1246 S.S.S. ~~Springfield, Missouri 65805~~

City, State, Zip Springfield, Missouri 65805

TENTATIVE DISPOSITION

	Check Off	Action Agency EPA	State	Local	Private
1) NO ACTION NEEDED - NO HAZARD	/__/				
2) INVESTIGATIVE ACTION(S) NEEDED If yes, fill in Page 2	/__/	/__/	/__/	/__/	/__/
3) REMEDIAL ACTION NEEDED If yes, fill in page 3	/X/	/X/	/X/	/__/	/__/
4) ENFORCEMENT ACTION NEEDED If yes, specify whether the case will be primarily managed by the EPA or the State.	/__/	/X/	/__/		
		/__/	/__/		

Rationale for disposition: Syntex Agribusiness via a contractor has developed and conducted pilot studies on a reductive-dechlorination process to detoxify the TCDD. Region VII is monitoring Syntex Agribusiness progress.

Indicate the estimated date of Final Disposition: July 31, 1980 ?

If a Case Development Plan is necessary, indicate the estimated date on which the Plan will be developed: _____

File this form in the regional Hazardous Waste Log File and submit a copy to:

Site Tracking System
Hazardous Waste Enforcement Task Force
U. S. Environmental Protection Agency
401 M Street SW (EN335)
Washington, D. C. 20460

Prepared by R

Telephone _____

Date _____

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INVESTIGATIVE ACTIVITY NEEDED

Identify additional information needed to achieve a final disposition:

Company must submit detailed design plans and specifications, operating protocols, contingency plans to EPA, OSHA and State review and acceptance prior to proceeding to process this waste.

METHOD FOR OBTAINING NEEDED ADDITIONAL INFORMATION	Scheduled Date of Action	To Be Performed by (EPA, Contractor, State, etc)	Estimated Manhours	Remarks
SITE INSPECTIONS				
MONITORING				
SAMPLING				
LAB ANALYSIS				
OTHER				
Syntex Agribusiness provided Action Plan ~~work~~ on 9-26-79		EPA/State	220	Region VII and State monitoring Syntex progress.

Please elaborate on any of the above as needed to identify additional investigative work:

Action Agency	Total Estimated Manhours for Investigative Activities
EPA	200 as of 10-30-79
State	40
Contractor	

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REMEDIAL ACTIONS

SHORT TERM/EMERGENCY STRATEGY (On site and off-site)

List all emergency actions needed to bring site under immediate control, e.g. restrict access, provide alternate water supply, etc. See instructions for a list of Key Words for each of the actions to be used in the spaces below.

ACTION	Est. Action Start Date	Est. Action End Date	Action Agency (EPA, State, Private Party)	Estimated Cost	Specify 311 or other action; indicate the magnitude of the work required:
				$	
				$	
				$	
				$	
				$	
				$	

LONG TERM STRATEGY (On site and off-site)

List all long term solutions, e.g. excavation, removal, ground water monitoring wells, etc. See instructions for a list of Key Words for each of the actions to be used in the spaces bel

ACTION	Est. Action Start Date	Est. Action End Date	Action Agency (EPA, State, Private Party)	Estimated Cost	Specify 311 or other action; indicate the magnitude of the work required:
Waste Processing	July 1980	~~Sept 80~~	Private	$ Unknown	Reduce Declassification Powers
Residual Incineration	Sept 80	Unknown	EPA	$ Unknown	Use EPA mobile incinerator.
				$	
				$	
				$	
				$	

Action Agency	Total Estimated Manhours for Remedial Activities	Total Estimated Cost for Remedial Activities
EPA		$
State		$

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U. S. ENVIRONMENTAL PROTECTION AGENCY

POTENTIAL HAZARDOUS WASTE SITE LOG

ne initial identification of a potential site or incident should not be interpreted as a inding of illegal activity or confirmation that an actual health or environmental threat xists. All identified sites will be assessed under the EPA's Hazardous Waste Site Enforcement and Response System to determine if a hazardous waste problem actually exists.

Site number _____

Site Name Vienna, Missouri, Syntex ~~Chemical~~ Dioxin Waste Storage Site

City, State, Zip Vienna, Missouri

Summary of potential or known problem: Storage Tank ~~contains~~ contains ~~4,800~~ 4,300 gallons of residue containing 343 ~~ppm~~ 117 ppm TCDD, ~~Dioxin~~

	Date of Determination or Completion	Responsible Organization or Individual (EPA, State, Contractor, Other)	Person Making Entry to Log Form
1. Identification of Potential Problem	1971	EPA Region VII	Kenneth S Ritter
2. Preliminary Assessment	1979	EPA Region VII	Kenneth S Ritter
2a. Apparent Seriousness of Problem	/X/ High* /__/ Medium /__/ Low /~~X~~/ None /__/ Unknown		
3. Site Inspection	1979	EPA Region VII	Kenneth S Ritter
4. EPA Tentative Disposition (check appropriate item)	_____		
a. No Action Needed /__/		Not Applicable	_____
b. Investigative Action Needed /__/		_____	_____
c. Remedial Action Needed /X/		Syntex Agribusiness	Kenneth S Ritter
d. Enforcement Action Needed /__/		_____	_____
5. EPA Final Strategy Determination (check appropriate item)	_____		
a. No Action Needed /__/		Not Applicable	_____
b. Remedial Action Needed /__/		_____	_____
c. Remedial Action Needed but No Resources Available /__/		Not Applicable	_____
d. Enforcement Action /__/		_____	_____
i. Case Development Plan Prepared /__/		_____	_____
ii. Enforcement Case Filed or Administrative /__/		_____	_____

*Except to environment,

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